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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. RUTHIA HE, A/K/A RUJIA HE, and DAVID BRODY, Defendants.	CASE NO. 3:24-cr-00329-CRB **[AMENDED]** **DEFENDANT RUTHIA HE'S TRIAL BRIEF RE: APPLICABLE LEGAL STANDARD FOR 21 U.S.C. §§ 841(a), 846**

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In advance of expert testimony, Ms. He submits this supplemental trial brief on the applicable legal standard for 21 U.S.C. §§ 841(a), 846, Counts I-V.

The critical legal issue in this case is the applicable standard, and consequent jury instructions, for the alleged violations of the Controlled Substances Act ("CSA") where, as here, the at-issue conduct involves prescriptions issued by licensed medical professionals. The Government concedes, as it must, that "[i]t is not enough for the United States to prove that a practitioner committed malpractice, intentional or otherwise." Gov't's Revised Proposed Jury Instructions, ECF 380 at 60. Indeed, "'an instruction is improper,'" this Court has held, "'if it allows a jury to convict a licensed practitioner'"—and, by extension here, Ms. He under an aiding and abetting or conspiracy theory—"'solely on a finding that he has committed malpractice, intentional or otherwise. Rather, the District Court must ensure that the benchmark for criminal liability is higher – the higher showing that the practitioner intentionally has distributed controlled substances for no legitimate medical purpose and outside the usual course of professional practice.'" *See* Ex. A (Tr. at 4512:14-22, *United States v. Napoli*, No. 3:10-CR-642-CRB, ECF 1067 (N.D. Cal. Nov. 9, 2012) (Breyer, J.), *aff'd United States v. Carozza*, 608 F. App'x 532 (9th Cir. 2015) (quoting *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006)). As this Court explained:

> I'm concerned about it [the applicable language for the jury charge] because *you can't have a defendant*, a doctor, *convicted* if he was careless, *if he committed malpractice*, *intentional or not*. He said, look, I don't care what the rules of medicine are…I'm going to chop off this person's leg…that's malpractice.
>
> *But that's not what this case is about*. *What this case is about is essentially drug pushing*…
>
> Let me tell the Government something: If you haven't proven that, you don't deserve to win….
>
> And so I'm of the opinion that if the jury returns a verdict of guilty in this case…*I want to make sure they use the proper standard*. I don't want there to be an argument down the line that, you know, they had a hard time trying to figure out and, gee, they wouldn't want to go to a doctor who – treating people this particular way and, boy, he was really careless and so forth and so on.

Id. at 4514: 7-15 & 18-19 – 4515: 5-12 (emphases added). The Court went on to instruct the jury, following the Ninth Circuit's decision in *Feingold*, 454 F.3d at 1010, that: "It is not enough for the United States to prove that a practitioner committed malpractice, intentional or otherwise. Rather, the United states must prove that the physician used his prescription-writing powers *as a means to engage in illicit drug dealing and trafficking*." *See* Ex. B (*Napoli* Jury Instructions, ECF 1056 at 17) (emphasis added).

As set forth below, consistent with *Napoli*, the statutory text and case law make clear that the dividing line between "malpractice, intentional or otherwise" and the "higher" "benchmark for criminal liability" is proof of knowledge or intent to act as an illicit drug dealer instead of a medical professional.

Moreover, although proof of the higher benchmark for criminal liability requires, *at a minimum*, knowledge or intent to act "without a legitimate medical purpose" *and* "outside the usual course of professional practice," as this Court found, *see* Ex. A (Tr. at 4512:18-22), and instructed the jury in *Napoli*, *see* Ex. B (ECF 1056 at 23 & 25), the modifiers "*legitimate* medical purpose" and "*usual* course of professional practice" are not found in the relevant provisions of the CSA and are instead supplied by a regulation, 21 C.F.R. § 1306.04(a), that does not govern here. Accordingly, the regulation's modifiers—"legitimate" and "usual"—should not define the scope of criminal liability under the statute, particularly because they are evocative of a civil negligence standard (or less) that risks confusing the jury about the critical distinction between "malpractice, intentional or otherwise" and the higher benchmark for criminal liability. Instead, consistent with the CSA and the case law, the requisite proof should be knowledge or intent to act without a medical purpose and outside the course of professional practice, as at least one court instructed the jury on remand from the Supreme Court's decision in *Ruan v. United States*, 597 U.S. 450 (2022). *See* Jury Instruction No. 20, *United States v. Kahn*, 17-cr-00029, ECF No. 1310 at 25–26 (D. Wyo. Dec. 15, 2023).

A. The dividing line between criminal and non-criminal conduct is knowledge or intent to act as a drug dealer rather than a medical provider.

As the Court is aware, the CSA makes it a crime to knowingly or intentionally distribute a controlled substance "except as authorized by this subchapter." 21 U.S.C. § 841(a). A practitioner who is registered under the CSA is "authorized" to issue prescriptions for controlled substances "in the course of professional practice." 21 U.S.C. §§ 802(21); *see also* §§ 822(b); 823(g)(1); 829(c). A registered practitioner acts in the course of professional practice when she practices medicine—that is, when she "act[s] for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury." *Ruan*, 597 U.S. at 479 (Alito, J., concurring in the judgment).

In the context of the CSA, "authorization plays a 'crucial' role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct." *Id.* at 459. The statute "bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," but it does not "regulate the practice of medicine [more] generally." *Gonzalez v. Oregon*, 546 U.S. 243, 270 (2005). It is to that end that the Ninth Circuit—and this Court—have made clear that the CSA does not permit a jury to convict a medical professional "solely on a finding that he has committed malpractice, intentional or otherwise." *Feingold*, 454 F.3d at 1010; *see also* Ex. A (*Napoli* Tr. at 4512:14-17). Rather, to convict a practitioner under § 841(a), the jury must "make a finding of intent not merely with respect to distribution, but also with respect to the *doctor's intent to act as a pusher rather than a medical professional*." *Feingold*, 454 F.3d at 1008 (emphasis added); *see also United States v. Rosenberg*, 515 F. 2d 190, 197 (9th Cir. 1975) (approving of jury instructions in a CSA case that "stressed" that "the jury had to look into [the defendant's] mind to determine whether he prescribed the pills for *what he thought was a medical purpose* or whether he was passing out the pills to anyone who asked for them") (emphasis added); *id.* at 193 ("Our examination of the legislative history convinces us that … Congress was concerned with the diversion of drugs out of

legitimate channels of distribution…The legislative history expressly states that the Act 'provides severe criminal penalties *for persons engaged in illicit . . . sale of controlled drugs* primarily for the profits to be derived therefrom.' Since this is what Dr. Rosenberg did, the severe criminal penalties contained in section 841 were appropriately applied to him.") (emphasis added).

The Supreme Court's decision in *Ruan* likewise supports the key distinction between proof of intentional malpractice and the higher benchmark for criminal liability, although it addressed the different question of whether Section 841's "knowingly or intentionally" *mens rea* applied to the statute's "except as authorized" clause rather than the meaning of that clause. 597 U.S. at 454-55. In *Ruan*, the majority rejected the Government's proposed standard which would have defined guilt based on whether a doctor attempted to conform his conduct to what "his fellow doctors would view as medical care." *Id.* at 465 (emphasis omitted). Rather, as the concurrence articulated, "[f]or a practitioner to 'practice medicine'"—and thus fall on the non-criminal side of the line—"he or she must act for a medical purpose – which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury – and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury." *Id*. at 479 (Alito, J., concurring). "A doctor who makes negligent or even reckless mistakes in prescribing drugs is still 'acting as a doctor'—he or she is simply acting as a *bad doctor*." *Id.* By contrast, when a doctor "knowingly or purposefully issues a prescription to facilitate 'addiction and recreational abuse,'" he does not "'act[] as a physician' in any meaningful sense" and may be held criminally liable. *Id.* (quoting *Gonzalez*, 546 U.S. at 274).

Thus, the key distinction in a CSA prosecution involving a medical provider is whether the provider acted as a medical professional (even as a "*bad doctor*," *Ruan*, 597 U.S. at 479 (Alito, J., concurring)), or instead knowingly or intentionally acted as a drug pusher or trafficker. This Court underscored that key distinction in *Napoli* by instructing the jury there, consistent with Ninth Circuit precedent—and as Ms. He has requested that the Court instruct the jury here—that "[i]t is not enough for the United States to prove that a practitioner committed malpractice, intentional or otherwise. Rather, the United States must prove that the physician used his prescription-writing

powers as a means to engage in illicit drug dealing and trafficking." *See* Ex. B (*Napoli* Jury Instructions at 17:16-19, ECF 1056); Gov't's Revised Proposed Jury Instructions, ECF 380 at 63 & 65 (Ms. He's proposed instructions based on *Napoli*).

B. The regulation does not define the scope of criminal liability under the CSA.

As explained above, a conviction under the CSA requires proof that a defendant knew that she was acting in an unauthorized manner, or intended to do so. Courts—including this Court and the Ninth Circuit—have given or approved jury instructions that rely on a regulation to define authorization. The regulation provides that "[a] prescription for a controlled substance to be effective must be issued for a *legitimate* medical purpose" by a licensed practitioner "acting in the *usual* course of his professional practice." 21 C.F.R. § 1306.04(a) (2021) (emphasis added). But the italicized language does not appear in the relevant statutory text, and the Ninth Circuit has not specifically addressed whether the italicized language is appropriate.

The relevant statutory provisions do not contain the words "legitimate" or "usual." The CSA does not use the words "medical purpose" with respect to Schedule II controlled substances, and in reference to Schedule V controlled substances, states that such drugs may not "be distributed or dispensed other than for a *medical purpose*" with no additional modifier regarding "legitim[acy]." 21 U.S.C. § 829(c); *accord Ruan*, 597 U.S. at 479 (Alito, J., concurring) ("For a practitioner to 'practice medicine,' he or she must act for a *medical purpose*—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury."). Similarly, a practitioner who is duly registered under the CSA is authorized to issue prescriptions for controlled substances "in the course of [his] *professional practice*"—not the "usual course of professional practice." *See* 21 U.S.C. § 802(21) (defining "practitioner" as "a physician … or [someone] otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research."); *United States v. Moore*, 423 U.S. 122, 141 (1975) (describing 21 U.SC. § 802(21),

there referenced as 21 U.S.C. § 802(20), as "defin[ing] the term 'practitioner' for purposes of the Act … [and] the type of registration contemplated by the Act" without reference to the regulation); *see also* 21 US.C. §§ 822(b), 823(g), 829(c).

Moreover, the regulation does not expressly refer to "authorization" for purposes of Section 841. Nor could the regulation purport to define the scope of criminal liability under the CSA. "[T]he Supreme Court [has] made clear … that a criminal conviction for violating a regulation is permissible only if a statute explicitly provides that violation of that regulation is a crime." *United States v. Alghazouli*, 517 F.3d 1179, 1184 (9th Cir. 2008). Section 841, however, refers only to the statute itself in describing authorization ("except as authorized by this subchapter…")—it does not suggest that the scope of the criminal prohibition may be determined by regulation. And in fact, 21 U.S.C. § 821 only authorizes the Attorney General "to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances"—not to impose criminal penalties under § 841. For all of these reasons, a violation of § 1306.04 subjects a practitioner to the civil penalties in 21 U.S.C. § 842(a)(1), but it does not define the scope of the criminal prohibition in § 841. *See* 21 C.F.R. § 1306.01 (limiting the scope of Part 1306 to "[r]ules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829)"); 21 U.S.C. § 842(a)(1) (imposing its penalties on "any person … who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829").

As such, § 1306.04's modifiers—"legitimate" and "usual"—should not define the CSA's authorization exception. While courts have used the terms "legitimate" and "usual" as a "'reference to objective criteria' that may serve as circumstantial evidence of a defendant's subjective intent to act in an unauthorized manner," those extra-statutory terms risk confusing the jury. *See United States v. Kahn*, 58 F.4th 1308, 1315-16 (10th Cir. 2023). There is a significant risk that the jury could interpret these modifiers in a manner evocative of the civil negligence standard of care—or an even less stringent standard—thereby allowing a conviction when a

medical provider fails to cross the line from "malpractice, intentional or otherwise" to criminal drug trafficking.[1]

On this basis, in *Kahn*, in the retrial on remand from *Ruan*, the court granted the physician defendant's request that the terms "legitimate" and "usual" be omitted from the jury instructions in his CSA prosecution as both terms might be evocative of the civil medical care standard to a lay jury. *See* ECF 1203 at 21-22; Tr. Transcript, United States v. Kahn, 17-cr-00029-ABJ (D. Wyo.) filed as Appx. Vol. XXI, at 51:11–52:7, *United States v. Kahn*, 2:17-cr-29 (10th Cir.). Instead, the court required the jury to find in relevant part:

> To be authorized under the law, a controlled substance prescription must be issued by an individual practitioner *acting in the course of professional practice*. For purposes of a registered practitioner, *to act in the course of professional practice means to practice medicine*. For a practitioner to practice medicine, *he or she must act for a medical purpose*—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury.
>
> Conversely, a prescription *is not authorized when it is issued for a purpose foreign to medicine*, *such as facilitating addiction*, *recreational abuse*, *or unlawful distribution*.
>
> However, issuing an unauthorized prescription (that is, a prescription not issued for a medical purpose while acting in the course of professional practice) is not, by itself, a crime. A registered practitioner only violates Title 21, United States Code, Section 841(a)(1) if he or she knowingly or intentionally issues an unauthorized prescription and, at the time, knew the prescription was unauthorized or intended it to be unauthorized.

[1] Not even civil malpractice cases require a doctor's chosen course of conduct to be "legitimate" or "usual." "The existing standard [for negligence] does not fault a medical professional for choosing among different methods that have been approved by the profession even if the choice later turns out to have been the wrong selection or not favored by other members of the profession." *Feao v. Ponce*, 696 F. Supp. 3d 887, 914 (C.D. Cal. 2023) (citing *Veasley v. United States*, 201 F. Supp. 3d 1200, 1200 (S.D. Cal. 2016)). Further, "the testimony of other physicians that they would have followed a different course of treatment than that followed by the defendant is not sufficient to establish malpractice." *Harris v. United States*, No. 19-cv-00248-TUC-DCB, 2021 WL 2334385, at *4 (D. Ariz. June 8, 2021).

Id. (emphases added).

Consistent with the CSA and the case law, the requisite proof should be knowledge or intent to act without a medical purpose and outside the course of professional practice, as *Kahn* instructed the jury, and Ms. He will submit revised proposed instructions in advance of the charge conference reflecting this modified request. Removing the modifiers "legitimate" and "usual," together with a *Napoli*-based charge instructing the jury that "the United states must prove that the physician used his prescription-writing powers as a means to engage in illicit drug dealing and trafficking," *see* Ex. B (ECF 1056 at 17), gives effect to the critical distinction between "malpractice, intentional or otherwise" and the higher benchmark for criminal liability. *See* Ex. A (*Napoli* Tr. at 4512:14-19).

C. At a minimum, proof of intent to act without a legitimate medical purpose *and* outside the usual course of professional practice is required.

If the Court instead hews to the plain language of the regulation—which includes these modifiers—*at a minimum*, proof of knowledge or intent that a medical professional acted without a legitimate medical purpose *and* outside the usual course of medical practice is required. *See* Gov't's Revised Proposed Jury Instructions, ECF 380 at 52-57; 62-67. The Government's proposed disjunctive construction, *see id.* at 46-47 & 60, is not only contrary to Ninth Circuit precedent, but would render portions of Section's 1306.04(a) language superfluous, undermining the critical distinction between "malpractice, intentional or otherwise" and the higher benchmark for criminal liability that the Government acknowledges applies here. *See* Ex. A (*Napoli* Tr. at 4512:14-19).

The parties have disagreed as to whether the instructions should require the Government to prove knowledge or intent to issue a prescription *both* without a legitimate medical practice *and* outside the usual course of professional practice, or whether (as the Government contends) only one of those showings must be made. Ms. He incorporates here her prior arguments regarding why the conjunctive construction is correct and consistent with Ninth Circuit precedent, as well as this Court's prior instructions. *See* Gov't's Revised Proposed Jury Instructions, ECF 380 at 54–

57; *see, e.g., United States v. Diaz*, 876 F.3d 1194, 1196 (9th Cir. 2017); *Feingold*, 454 F.3d at 1012; *United States v. Pham*, 120 F.4th 1368, 1371 (9th Cir. 2024); *see also Rosenberg*, 515 F. 2d at 197 (approving of jury instructions that not only "stressed" that "the jury had to look into [the defendant's] mind to determine *whether he prescribed the pills for what he thought was a medical purpose*" but also "in no way indicated that the jury could find [the defendant] guilty if it found that he *either* acted not in the course of his professional practice *or* not for legitimate medical reasons") (emphases added).

Conversely, the Government's either/or construction would violate the canon that "enactments should not be construed to render their provisions mere surplusage." *See, e.g.*, *Am. Vantage Cos. v. Table Mountain Rancheria*, 292 F.3d 1091, 1098 (9th Cir. 2002) (quoting *Dunn v. Commodity Futures Trading Comm'n*, 519 U.S. 465, 472 (1997)). Instead, courts should "give effect, if possible, to every clause and word of a statute." *United States v. Allergan, Inc.*, 46 F.4th 991, 999 (9th Cir. 2022). Here, given the plain language of the regulation, this means requiring the Government to prove knowledge or intent that that the medical professional acted without a medical purpose *and* outside the course of professional practice. Even the Government's proposed instructions include both the phrase "for a legitimate medical purpose" and the phrase "in the usual course of professional practice," and in one instance the conjunctive language Ms. He proposed. *See* Gov't's Revised Proposed Jury Instructions, ECF 380 at 43 (proposing to instruct the jury that there was an agreement to distribute controlled substances "not for a legitimate medical purpose in the usual course of professional practice"), *id.* at 59 (proposing to instruct the jury that "'[u]nauthorized matter' means that the distribution of the controlled substance was outside of the usual course of professional practice *and* without a legitimate medical purpose") (emphasis added).

The Government has argued that *Ruan* suggests that it need only make one of those showings. Gov't's Revised Proposed Jury Instructions, ECF 380 at 47–48. Not so. As noted, *Ruan* addressed the *mens rea* element; it did not specifically address the meaning of the "except as authorized" clause. *Ruan* nonetheless supports the conjunctive construction, because it explains that the regulation "defin[es] the scope of a doctor's prescribing authority … [with] reference to

objective criteria such as 'legitimate medical purpose' *and* 'usual course' of 'professional practice.'" *Ruan*, 597 U.S. at 467 (emphasis added). Moreover, in requiring a *higher mens rea* standard, the Court expressed concern with "the risk of 'overdeterrence,' *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line." *Id.* at 459. Requiring the Government to prove that a medical practitioner acted *both* without a medical purpose *and* outside the course of professional practice is important to "diminish" that risk. *Id.*

Both of those concepts go to the ultimate statutory question of whether there is the requisite proof of knowledge or intent that the distribution is unauthorized. The Government's attempt to cleave those concepts from one another risks confusing the jury and lowers the burden of proof.

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